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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
01/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/18/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35,37 and 47-53* is/are pending in the application.

4a) Of the above claim(s) *48 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-35,37,47,49,50,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18 2008 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the surface capillary fiber having a channel along its outer side that extends substantially parallel to the length of the surface capillary fiber.

Claim Objections

3. Claim 33 is objected to because of the following informalities: Claim 33 recites the limitation "the inner surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 28-31, 33-35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Deniega et al (U.S. Patent No. 6,350,253). Deniega et al disclose a tubular medical device (52) comprising a tubular substrate having an interior surface, an exterior surface, and a plurality of surface capillary fibers (54) associated with at least a portion of one of the surfaces with an adhesive or chemical bonding. The tubular porous membrane of Deniega et al is a plurality of surface capillary fibers (54) as the membrane is porous, i.e., formed of a plurality of pores, and thus formed of a plurality of surface capillary fibers. In lines 42-44 of column 9, Deniega et al disclose the plurality of surface capillary fibers being associated with at least a portion of the interior or inner surface of the medical device (52) with an adhesive bond such as epoxy. The tubular medical device is a catheter or a microcatheter. The surface capillary fibers are associated with a bioactive agent (lines 47-63 of column 9). As to claim 34, Deniega et al disclose a medical device (52) comprising a non-porous surface where at least a portion of the surface is covered with surface capillary fibers and where the surface is contoured to match a portion of a structure within a patient. The non-porous surface comprises a polymer (lines 1-6 of column 9). The surface capillary fibers are associated with a bioactive agent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 20, 25-27, 47, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Drobish et al (U.S. Patent No. 4,623,329). In Figure 6, Deniega et al show a medical device (52) with a surface capillary fiber (54) comprising a polymer (lines 35-38 of column 9). In lines 47-63 of column 9, Deniega et al disclose a quantity of bioactive agent associated with the surface capillary fiber where the bioactive agent elutes in a controlled way from the fiber when the surface capillary fiber is contacting a patient's body fluids/tissue. The surface capillary fiber is considered to have a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter. The device is configured for placement within a blood vessel without blocking flow through the vessel. The device comprises a catheter and additional surface capillary fibers which are associated with the inner surface of the catheter as seen in Figure 6. The tubular porous membrane of Deniega et al comprises a surface capillary fiber and additional surface capillary fibers (54) as the membrane is porous, i.e., formed of a plurality of pores, and thus formed of a plurality of surface capillary fibers. As to claims 47, Deniega et al disclose a method for delivering a bioactive agent where a patient's body fluids/tissues contact a surface capillary fiber associated with the bioactive agent (lines 47-63 of column 9) and where

the bioactive agent elutes in a controlled way from the fiber. Deniega et al disclose the device and method substantially as claimed. Even though Deniega et al disclose fluid diffusing longitudinally within the wall of the tubular porous membrane or the surface capillary fiber such that the pores would extend along at least a portion of the length of the surface capillary fiber, Deniega et al are silent as to the specifics of the surface capillary fiber having a channel along its outer surface that extends substantially parallel to the length of the surface capillary fiber and the channel extending along at least a portion of the length of the surface capillary fiber. Drobish et al disclose a medical device comprising a surface capillary fiber (2) comprising a polymer and a quantity of bioactive agent associated with the surface capillary fiber (lines 28-32 of column 6 and lines 32-41 of column 7). Drobish et al teach that the surface capillary fiber has a channel (16) along its outer surface that extends substantially parallel to the length of the surface capillary fiber and the channel extends along at least a portion of the length of the surface capillary fiber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the outer surface of the surface capillary fiber of Deniega et al with a channel that extends substantially parallel to the length of the surface capillary fiber such that the channel would extend along at least a portion of the length of the surface capillary fiber as taught by Drobish et al as both Deniega et al and Drobish et al disclose a medical device with a surface capillary fiber and a bioactive agent associated with the surface capillary fiber where the bioactive fluid diffuse or elutes in a longitudinal direction and Drobish et al teach that it is well known to provide the outer surface of the surface capillary fiber with a channel that

would allow the fluid to elute in a controlled way from the fiber and along the length of the device (lines 32-41 of column 7).

8. Claims 21, 22, 24, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Drobish et al as applied to claims 20 and 47 above, and further in view of DiCarlo et al (U.S. Patent No. 6,929,626). Deniega et al and Drobish et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent being a thrombolytic agent such as heparin sulfate or a microbial agent. DiCarlo et al disclose a medical device (10) with surface capillary fibers (18, 22) where a bioactive agent is associated with the surface capillary fibers (lines 1-23 of column 13). DiCarlo et al disclose the bioactive agent comprising a thrombolytic agent, a microbial agent, or heparin sulfate (lines 24-44 in column 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as heparin sulfate or a microbial agent as taught by DiCarlo et al as both Deniega et al and DiCarlo et al disclose medical devices with surface capillary fibers and a bioactive agent associated with the surface capillary fibers and DiCarlo et al teach that it is well known to use a thrombolytic agent such as heparin sulfate or a microbial agent for the bioactive agent which is being delivered into the patient's body.

9. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of DiCarlo et al (U.S. Patent No. 6,929,626). Deniega et al disclose the

device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent being a thrombolytic agent such as heparin sulfate. DiCarlo et al disclose a medical device (10) with surface capillary fibers (18, 22) where a bioactive agent is associated with the surface capillary fibers (lines 1-23 of column 13). DiCarlo et al disclose the bioactive agent comprising a thrombolytic agent, a microbial agent, or heparin sulfate (lines 24-44 in column 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as heparin sulfate or a microbial agent as taught by DiCarlo et al as both Deniega et al and DiCarlo et al disclose medical devices with surface capillary fibers and a bioactive agent associated with the surface capillary fibers and DiCarlo et al teach that it is well known to use a thrombolytic agent such as heparin sulfate or a microbial agent for the bioactive agent which is being delivered into the patient's body.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Drobish et al as applied to claim 20 above, and further in view of Samson et al (U.S. Patent No. 6,066,149). Deniega et al and Drobish et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent comprising tissue plasminogen activator (tPA). Samson et al disclose using a medical device or catheter to deliver bioactive agents such as tPA or urokinase (lines 19-27 of column 5) which are thrombolytic

agents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Deniega et al a thrombolytic agent such as tPA as taught by Samson et al as both Deniega et al and Samson et al disclose medical device for delivering a bioactive agent and Samson et al teach that it is well known to use a thrombolytic agent such as tPA for the bioactive agent which is being delivered into the patient's body.

11. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deniega et al in view of Drobish et al as applied to claim 20 above, and further in view of Bucay-Couto et al (U.S. Patent Application Publication No. 2003/0018306). Deniega et al and Drobish et al disclose the device and method substantially as claimed. Even though Deniega et al disclose a bioactive agent or medication associated with the surface capillary fiber(s), Deniega et al are silent as to the specifics of the bioactive agent being associated with a controlled release agent. Bucay-Couto et al disclose using a medical device or catheter to deliver bioactive agents and teach associating the bioactive agent with a controlled release agent in order to control the release of the bioactive agent (paragraph [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to associate the bioactive agent of Deniega et al with a controlled release agent as taught by Bucay-Couto et al as both Deniega et al and Bucay-Couto et al disclose medical device for delivering a bioactive agent and Bucay-Couto et al teach that it is well known to use a controlled release agent with the bioactive agent in order to extend the release time of the bioactive agent.

Response to Arguments

12. Applicant's arguments with respect to claims 20-33, 47, and 52 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments filed December 18 2008 have been fully considered but they are not persuasive. As to Applicant's arguments in lines 1-5 of page 8 regarding the prior art rejection of claim 34, the non-porous surface of Deniega et al is considered to be contoured because the surface has an outline and is curved as seen in the figures (see Figures 5-7). In response to applicant's argument that Deniega et al does not teach a medical device contoured to match a portion of a structure within a patient, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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